DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1359]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Affirmation of Generally Recognized as Safe (GRAS) Status

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Affirmation of Generally Recognized As Safe (GRAS) Status (21 CFR 170.35(c)(1)) (OMB Control Number 0910–0132)—Extension

Under the authority of sections 201, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 342, 348, and 371), FDA reviews petitions for affirmation as GRAS that are submitted on a voluntary basis by the food industry and other interested parties. Under section 409 of the act, the agency has the authority to regulate food additives. Section 201(s) of the act defines ''food additive'' and expressly excludes from the definition substances GRAS for use in food.

Specifically under section 201(s) of the act, a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The act has historically been interpreted to permit food manufacturers to make their own determination that use of a substance in food is GRAS. To implement the GRAS provisions of the act, FDA has issued procedural regulations under § 170.35(c)(1) (21 CFR 170.35(c)(1)). These regulations establish a process by which a person may obtain FDA concurrence with a GRAS determination; this concurrence is referred to as ''GRAS affirmation.'' These regulations set forth the information to be submitted to FDA to obtain agency concurrence that a substance is GRAS (§ 170.35(c)(1)).

GRAS petitions are reviewed by FDA to ascertain whether the available data establish that the intended use of the substance is GRAS based upon either a history of the safe use of the substance, or upon widely available safety data (scientific procedures). The GRAS affirmation process is a voluntary one, and there is some risk that FDA may not agree with the petitioner's GRAS determination. The GRAS petition process does provide a public procedure for coordinating GRAS determinations. The process reduces the potential for public health problems when substances are marketed based upon unwarranted safety determinations and allows a food manufacturer to rely on the lawful status of a substance that has been affirmed by FDA as GRAS.

In the **Federal Register** of July 5, 2000 (65 FR 41472), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.35(c)(1)	1	1	1	2,614 (average)	2,614

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that it may receive one GRAS petition annually. Although the burden varies with the type, size, and complexity of the petition submitted, GRAS petitions may involve analytical work, analysis of appropriate toxicological studies, and the work of drafting the petition itself. Since 1980, FDA has not received any petitions for affirmation of GRAS status under 21 CFR part 186—Indirect Food Substances Affirmed As Generally Recognized As Safe.

Section 184.1(a) (21 CFR 184.1(a)) affirms the use of those substances affirmed as GRAS in 21 CFR part 184—Direct Food Substances Affirmed As Generally Recognized As Safe, for use as indirect food ingredients.

Dated: September 19, 2000

William Hubbard

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Commissioner for Policy, Planning, and Legislation

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